

REMARKS

Status of the Claims

Claims 1-48 and 59-62 are currently pending in this application. Claims 12-13, 19, 22-23, 35-43, 50 and 59-62 have been withdrawn from consideration. Claims 1-11, 14-18, 20-21, 24-34, and 44-48 have been rejected. Reconsideration is respectfully requested.

Drawings

The Examiner states:

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 46a and 46b, as disclosed on page 13, line 7; and 505, as disclosed on page 17, line 12. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 9 - 143 and 151; Figure 10 - 110, 112b, 122a, 143 and 152; Figure 11 - 110, 112b, 122a, 143 and 152; Figure 12 - 241 and 243; Figure 13 - 222b, 241 and 242; Figure 14 - 314; Figure 15 - 314, 333c, 341 and 343; Figure 16 - 314, 333c, 341 and 343; Figure 17 - 314, 322a and 341; Figure 18 - 422, 441 and 442; Figure 19 - 422; Figure 20 - 422, 441, 442 and 443; Figure 21 - 522; Figure 22 - 522, 541, 542 and 543; Figure 23 - 522; Figure 24 - 641; Figure 25 - 641 and 643; Figure 26 - 641; Figure 27 - 712, 741 and 742; Figure 28 - 741 and 742; Figure 34 - 942; Figure 35 - 942; Figure 36 - 1352; Figure 37 - 1041; Figure 39 - 1181 a and 1181b; Figure 40 - 1246 and 1248; Figure 41 - 1246 and 1248; Figure 42 - 1311, 1341, 1342 and 1380; and Figure 43 - 1311, 1341, 1342, 1343 and 1380.

Applicant proposes drawing changes as specifically described in the Amendments to the Drawings section, and attached as both Annotated and Replacement Sheets for the Examiner's

consideration. Applicant further amends certain paragraphs in the specification to address the issues having to do with element numbers. Applicant believes that these changes and amendments address the issues raised by the Examiner.

Rejections Under 35 USC §112

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states:

Claim 33 recites the limitation "the means for preventing migration" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Applicant amends claim 33 to change its dependency from claim 29, which does not have antecedent basis for the cited element, to claim 30 which does. Applicant believes that this amendment addresses the Examiner's issue.

Rejections Under 35 USC §102

Claims 20-21 and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb (US Publication 2005/0027360). The Examiner states:

Webb discloses a surgical instrument system (Figures 13A and 13B) comprising an instrument (182) capable of maintaining a distraction between vertebrae including a shaft (186) and a paddle (184) having inferior and superior surfaces (see annotated Figure below) located on a distal end of the shaft; an implant inserter (190) having a distal end (i.e. tip of 192); and an access port (paragraph 0081), wherein the paddle and shaft present a guide surface (i.e. left surface of 184 as shown in Figure 10) and a guide feature (i.e. left surface of 186 as shown in Figure 10) for guiding the placement of the implant and interaction with the distal end of the inserter and an angled guide feature (see annotated Figure below) integral with the distal portion of the paddle to guide an implant (100) through a partial rotation to a desired angle and the paddle includes a first height (i.e. width of left surface of 184 as shown in Figure 10) and a second height (i.e. thickness of 184 as shown in Figure 13A) greater than the first height (Figures 10-13D and paragraphs 0072-0090).

With regard to the statements of intended use and other functional statements, such as "for" and "configured to," they do not impose any structural limitations on the claims distinguishable over Webb which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim 20 recites a distractor having a paddle and shaft wherein both the paddle and shaft present an inserter guide surface. Applicant has amended claim 20 to further recite an implant inserter that includes a corresponding feature that mates with the inserter guide feature that extends along the paddle and shaft so that the implant inserter can be guided by the distractor to the right place to insert the implant. Dependent claim 28, which recited similar features to claim 20 as amended, has now been canceled.

The inserter in Webb has no "corresponding feature" that mates with an inserter guide surface on a distractor. Instead, the Webb implant bumps against an angled paddle. Accordingly, Webb cannot anticipate independent claim 20. Because claims 21, 24-27, and 29-33 depend from claim 20, these claims are likewise patentable over Webb.

Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Han et al. (WO 02/17823 A1). The Examiner states:

Lim discloses a surgical instrument system (Figure 12) comprising an articulating implant inserter including a shaft (172) and an articulatable implant holding element (162) located on a distal end of the shaft operable from a proximal portion of the shaft to releasably hold (i.e. via 174) an implant (30), wherein the implant has a connecting element (46) internal to the implant that cooperates with the holding element to allow articulation of the implant to a desired angle, and the holding element includes two sliding elements (166/168 and 172) operable from a proximal handle (130) to provide the articulation of the implant to the desired angle (Figures 5 and 11-13 and page 14, line 26 - page 17, line 5).

Claims 44 and 46-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Lim (US Publication 2004/0153065). The Examiner states:

Lim discloses a surgical instrument system (Figure 10) comprising an articulating implant inserter (9) including a shaft (80) and an articulatable implant holding element (55) located on a distal end of the shaft operable from a proximal portion of the shaft to releasably hold (i.e. via 90) an implant (10), wherein the implant has a connecting element (93) external to the implant that cooperates with the holding element to allow articulation of the implant to a desired angle, and the holding element includes two sliding elements (81 and 82) having distal implant impaction faces operable from a proximal handle (130) to provide the articulation of the implant to the desired angle (Figures 10-16 and paragraphs 0035-0061).

Applicant has amended claim 44 to recite that “the articulatable implant holding element includes two sliding elements, each having a distal implant impaction face contacting the implant.” Lim is the only reference applied to claim 47, which recited much of the substance of this amendment (and which is now canceled). Lim provides two sliding elements, but neither contacts the implant. Instead, Lim provides a separate pivoting element that contacts the prosthesis. Accordingly, claims 44, 45, 46 and 48 cannot be anticipated by Lim – and the Examiner seems to agree that this subject matter is not disclosed by Han.

Rejections Under 35 USC §103

Claims 1-11, 15, 17-18 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb (US Publication 2005/0027360) in view of Nichols et al. (US Publication 2003/0149438). The Examiner states:

Webb discloses the claimed invention except for a filler bar to removably engage the shaft and paddle of the distractor, wherein the filler bar extends substantially along at least one side of the shaft and paddle, does not extend beyond the superior and inferior surfaces of the paddle and slidably engages the distractor along a longitudinal axis of the distractor. Nichols et al. teach an instrument (30) capable of maintaining a distraction between vertebrae including a shaft (31) and a paddle (25) and a filler bar (12) shaped to removably engage (i.e. by sliding) the shaft and paddle of the distractor (Figure 2 and paragraphs 0027-0031). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb with the instrument capable of maintaining a distraction between

vertebrae including a shaft and a paddle and a filler bar shaped to removably engage the shaft and paddle of the distractor in view of Nichols et al. in order to provide a safe and secure means for inserting an implant.

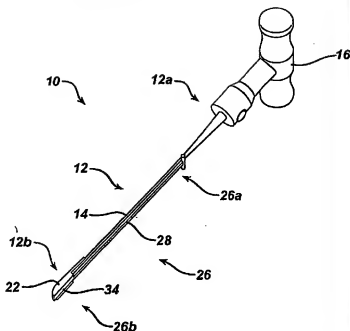
Webb in view of Nichols et al. disclose the claimed invention except for at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) to prevent the migration of the distractor during distraction. Webb discloses the implant (100) having protrusions / teeth / expansion shoulders (130) (Figure 3 and paragraph 0044). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb in view of Nichols et al. with at least one of the inferior and superior surfaces of the paddle including bone engaging elements (i.e. teeth / expansion shoulder) in order to penetrate the vertebral plate to inhibit the removal of the distractor during distraction.

Webb in view of Nichols et al. disclose the claimed invention except for the distal end of the inserter being angled to correspond with the angle of the angled guide feature. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Webb in view of Nichols et al. with the distal end of the inserter being angled to correspond with the angle of the angled guide feature in order to provide mating guide surfaces between the distractor and the inserter to reduce the overall profile of the combination, since the applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an angled distal end. In re Dailey and Eilers, 149 USPQ 47 (1966).

The Invention:

As restricted, the presently claimed invention relates to surgical instruments for distracting an intervertebral space, and in some claims also guiding an implant into that space.

An important tool in this system is the distractor assembly 10 illustrated in Figure 1, for example. The assembly 10 includes a distractor 12 and a filler bar 26. The distractor has a handle 16 on its proximal end, a distracting paddle 22 on its distal end, and a shaft 14 in between. The filler bar 26 mates with features on the distractor to provide rigidity and torque strength so that the distractor can be inserted between vertebrae 41,4 with the paddle horizontal, and then rotated approximately 90 degrees to distract the vertebrae using superior and inferior surfaces 22c, 22d of the paddle.

FIG. 1

Following distraction, the filler bar 26 can be removed from the distractor 12 to increase the amount of space available, as well as to increase the surgeon's visibility (the distractor 12 with the filler bar 26 removed is illustrated in Figure 2). In addition, an implant inserter can mate to the distractor using the same features that the now removed filler bar had mated to.

Response to the Rejection:

The Examiner essentially admits that the art has no rotating distractor having a filler bar as described. The Webb reference has a paddle tool having an angle at its distal end, but no filler bar. The Nichols reference has a two piece inserter tool. As the Examiner lays out the correspondence of the "filler bar" in the Nichols reference, no tool provided in this manner could work as a rotating distractor – the tool is wider than the paddle, making a rotating distraction impossible. Applicant has moved the recitations of claim 2 and claim 4 into the body of claim 1 – these features further define both the function of the instrument as well as the size of the filler bar with respect to the distractor – and there is no combination of Nichols and Webb that teaches such a tool. In addition, Applicant has added new claims 63 to 65 that further define the geometry of the filler bar (these claims are supported at least at page 12, lines 9 to 32 of the specification) – the combination of

Webb and Nichols likewise fails to teach a combination distractor/filler bar tool having these features.

CONCLUSION

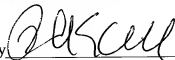
If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed with this paper, asserted to be filed with this paper or which were required to be filed with this paper to our Deposit Account No. 141449, under Order No. 101896-474.

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Respectfully submitted,

By 

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